UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

IN RE CYBERONICS INC. SECURITIES LITIGATION	§ § § § §	**Civil Action H-05-2121**

MEMORANDUM AND ORDER

Pending before the Court are Defendants' Motion to Dismiss Plaintiffs' Consolidated Complaint (Dkt. #36) and Plaintiffs' Motion to Take Judicial Notice of Certain Facts (Dkt. #40). Having considered the motions, the responses, and the applicable law, the Court is of the opinion that Defendants' Motion to Dismiss Plaintiffs' Consolidated Complaint should be GRANTED and Plaintiffs' Motion to Take Judicial Notice of Certain Facts should be GRANTED in part and DENIED in part.

Factual and Procedural Background

These consolidated cases constitute a putative securities fraud class action involving the stock of Defendant Cyberonics, Inc. ("Cyberonics"). The lawsuits arise out of Cyberonics' efforts to secure approval from the FDA for marketing a device for the treatment of depression. The proposed class consists of all purchasers of Cyberonics securities between June 15, 2004 and October 1, 2004 (the "class period").[1] The Lead Plaintiff is Cyberonics Investor Group, which is comprised of EFCAT, Inc., John E. & Cecilia Catogas, Blanca Rodriguez, and Mohamed Bakry. Defendants are Cyberonics and certain Cyberonics senior officers and directors from the class period, including Robert P. Cummins, Chairman and CEO; Richard L. Rudolph, Vice President of Clinical and Medical Affairs;

[1]The court refers to this as the "class period," although no class has been certified. *See Nathenson v. Zonagen Inc.*, 267 F.3d 400, 404 (5th Cir. 2001) (noting similarly that, "[d]espite the absence of certification, we will, for clarity's sake, refer to the time in question as the 'class period'").

Alan Totah, Vice President of Regulatory Affairs; Michael A. Cheney, Vice President of Marketing; W. Steven Jennings, Vice President of Sales; and Pamela B. Westbrook, CFO and Vice President of Finance and Administration (collectively "Defendants").

Cyberonics manufactures and sells the Vagus Nerve Stimulation Therapy System ("VNS Device"), a small device implanted beneath the skin and connected by a lead to the vagus nerve in the neck. The device delivers mild pulses of electrical energy. The FDA approved the device in 1997 for treatment of epilepsy. The device has also received regulatory approval in the European Union, Canada, Australia, and other countries.

In 1998, Cyberonics began to explore the use of the VNS Device to treat chronic depression, also known as treatment-resistant depression ("TRD"). In 2001, Cyberonics received regulatory approval from the European Union and Canada to market the VNS Device as a treatment for TRD. In October 2003, Cyberonics filed a Premarket Approval Supplement application ("PMA-S")[2] with the FDA, seeking approval to market the VNS Device in the United States as a treatment for TRD. An Advisory Committee of the FDA's Neurological Devices Panel met on June 15, 2004 to consider whether to make a formal recommendation that the FDA approve the PMA-S. After the meeting, the Advisory Committee voted to recommend approval of the VNS Device for the treatment of TRD.

On August 11, 2004, contrary to the Advisory Committee's recommendation, the FDA informed Cyberonics that its PMA-S was not approvable as submitted. The FDA's stated reasons included, in part, certain safety concerns, worsening depression, potential biases stemming from a

[2]A PMA Supplement is a supplemental application to a previously approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference. After approval of the original PMA, an applicant may submit a PMA Supplement addressing a new use of the device for review and approval by the FDA.

non-randomized control, and an inability to distinguish from placebo and treatment effects. After the non-approvable letter, Cyberonics' stock price dropped by approximately 40%. Thereafter, Advanced Neuromodulation Systems Inc. ("ANSI"), purchased a 14.9% stake in Cyberonics at the lowered prices with the intention of proposing a "business combination." In response, Cyberonics issued a press release on August 20, 2004 entitled, "Cyberonics Acknowledges ANSI Purchase of 3.5 Million Shares and Expresses No Interest In Any Merger or Combination." The press release stated in part: "Cyberonics is not interested in any combination or merger and remains focused on growing its epilepsy business and gaining clarity and certainty in a revised depression regulatory timeline. In the few days since learning of the FDA's decision, we are making good progress towards those objectives."

Over the next few months, Cyberonics provided the FDA with additional information concerning the PMA-S, and on February 2, 2005, the FDA reversed itself and determined the PMA-S was "approvable." The FDA formally approved the PMA-S on July 15, 2005, authorizing Cyberonics to sell the VNS Device for treatment of TRD. Plaintiffs filed this action on June 17, 2005, before the formal FDA approval. The Consolidated Complaint was filed on November 30, 2005, asserting claims under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5.

According to Plaintiffs, Defendants issued false and misleading statements during the class period regarding the approvability of the PMA-S for TRD, beginning with Defendants' press release and statements lauding the results of the June 15, 2004 FDA Advisory Panel vote in favor of the PMA-S. Plaintiffs insist that despite Defendants' positive statements about the Advisory Panel, a careful reading of the transcript points to a contentious panel review. Plaintiffs maintain the

Defendants' comments and statements following the Advisory Panel's decision were misleading, false, and made in conscious and reckless disregard of the panel members' concerns about whether Cyberonics had failed to satisfy FDA standards for safety and efficacy. Plaintiffs also contend that Defendants omitted material information by not disclosing an FDA inspection that began on July 12, 2004, after indicating in January 2004 that an FDA inspection would not occur.

In their complaint, Plaintiffs also allege that Defendants continually misrepresented the size of the potential market for the VNS Device's use in treatment for TRD. Moreover, Plaintiffs cite Defendants' conduct after receiving the non-approvable letter of August 2004. Specifically, Plaintiffs contend that Defendants' reaction concealed the fact that they knew, because of the progress of the inspection as well as ongoing communications with the FDA, that the FDA had significant reservations about the safety and effectiveness of the VNS Device for TRD treatment. Plaintiffs suggest that the allegations above and the others contained in their complaint suggest a manipulative effort on the part of Defendants to drive up share prices. Plaintiffs further submit that they, as well as other investors, were harmed by purchasing the shares at artificially inflated prices, which later dropped significantly after Defendants' alleged misrepresentations were revealed.

Defendants filed their Motion to Dismiss Plaintiffs' Consolidated Complaint on January 30, 2006. Plaintiffs responded and filed their Motion to Take Judicial Notice of Certain Facts on March 31, 2006.

Discussion

Defendants seek dismissal of all claims against them pursuant to Federal Rules of Civil Procedure Rule 9(b) and 12(b)(6). In response, Plaintiff submit that they have properly alleged claims under sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5. Plaintiffs further request

that the Court take judicial notice of certain facts and documents. The Court will address each motion below.

I. Plaintiffs' Motion to take Judicial Notice

Plaintiffs request that the Court take judicial notice of The United States Senate Committee Staff Report to Chairman Charles E. Grassly and Ranking Member Max Baucus of the Committee on Finance, entitled *Review of the FDA's Approval Process for the Vagus Nerve Stimulation Therapy System for Treatment-Resistant Depression* and dated February 2006 (the "Senate Report"). In response, Defendants assert that the Senate Report and its attachments do not meet the fundamental criteria for judicial notice. In particular, Defendants contend that the Senate Report is full of opinions, conclusions, and disputed facts that do not satisfy the requirements in Rule 201 that judicial notice be reserved for "facts" generally known or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. *See* FED. R. CIV. P. 201(b).

In their reply brief, Plaintiffs assert that "Defendants' arguments run far afield of the actual relief sought by Plaintiffs' Motion." According to Plaintiffs, "[t]he determination at issue, whether the Court should take judicial notice *merely of the existence of the Senate Report*, is easily dispensed."[3] Plaintiffs later remark that "the existence of the Senate Report *and the purpose, nature, substance and conclusions of the Senate Investigation* . . . cannot reasonably be questioned." As the obvious inconsistency of these two statements suggests, there is a significant difference between taking judicial notice of the existence of a report and taking notice of that report's contents, including its conclusions and the substantive basis outlined in support of the conclusions. While the former is appropriate for judicial notice in this case, the Court finds that the latter is not. In fact, the express

[3]Dkt. #45, p.2 (emphasis added).

language of the report indicates that the committee staff "did not independently assess the validity of the data submitted or determine whether or not the sponsor met the FDA's standards for approval of the VNS Therapy System."[4] Therefore, Plaintiffs' motion is GRANTED only to the extent it requests judicial notice be taken of the existence of a Committee Staff Report addressing the *FDA's Approval Process for Vagus Nerve Stimulation Therapy System for Treatment-Resistant Depression*. However, because the Senate Report itself contains findings, conclusions, disputed facts, and unverified data, which clearly do not satisfy the requirements of Rule 201(b), judicial notice of the contents of the Senate Report would be improper. To the extent Plaintiffs seek such relief, their motion is DENIED.

II. Defendants' Motion to Dismiss

Defendants assert that Rules 9(b) and 12(b)(6) entitle them to dismissal of the securities fraud claims against them. In particular, Defendants contest Plaintiffs' claims under sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 because: (1) Plaintiffs failed to plead a misrepresentation of material fact with particularity; (2) Plaintiffs failed to plead facts providing a strong inference of scienter; and (3) Plaintiffs have failed to plead loss causation. In response, Plaintiffs claim that the contents of their complaint—a sprawling 94-page document—satisfy the relevant pleading requirements. In the alternative, Plaintiffs seek leave to amend their complaint to remedy any defects and incorporate subsequently uncovered facts.

[4]Dkt. #42, p.4.

A. Standard of Review

A complaint should be dismissed for failure to state a claim under Rule 12(b)(6) if it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). In considering 12(b)(6) motions, courts generally must accept the factual allegations contained in the complaint as true. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982). In addition to the factual allegations, a court may take judicial notice of documents of public record, such as documents filed with the SEC, and may consider such documents in determining a motion to dismiss. *See R2 Investments LDC v. Phillips*, 401 F.3d 638, 640 n.2 (5th Cir. 2005) (citing *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996)).

To avoid dismissal, fraud claims under section 10(b) of the Exchange Act must also satisfy the heightened pleading requirements imposed by Rule 9(b) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u (1995) ("PSLRA"). Rule 9(b) states that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." FED. R. CIV. P. 9(b). "To satisfy Rule 9(b)'s pleading requirements, a plaintiff must 'specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent.'" *Southland Sec. Corp. v. Inspire Ins. Solutions, Inc.*, 365 F.3d 353, 362 (5th Cir. 2004) (quoting *Williams v. WMX Tech., Inc.*, 112 F.3d 175, 177 (5th Cir.1997)).

Under the PSLRA, a plaintiff must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement

or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); *see also R2 Investments LDC v. Phillips*, 401 F.3d 638, 640, 641-42 (5th Cir. 2005). Further, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Concerning the liability of individual defendants, "group pleading . . . is not permitted for PSLRA actions in [the Fifth] [C]ircuit." *Financial Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285 (5th Cir. 2006). Instead, "[p]laintiffs must distinguish among defendants and allege the role of each. Corporate officers are not liable for acts solely because they are officers, even where their day-to-day involvement in the corporation is pleaded." *Id.* at 287. However, "[c]orporate statements can be tied to officers if plaintiffs allege they signed the documents in which the statements were made or allege adequately their involvement in creating the documents." *Id.*

B. Analysis

Section 10(b) makes it illegal for a person to use or employ, in connection with the purchase or sale of any security, any manipulative or deceptive device or contrivance in contravention of the SEC's rules. Rule 10b-5 makes it unlawful for anyone to make a false statement of material fact or to omit a material fact necessary to make the statement not misleading. 17 C.F.R. § 240.10b-5. As previously noted, to state a claim under section 10(b) and Rule 10b-5, "a plaintiff must allege, in connection with the purchase or sale of securities[:] (1) a misstatement or an omission (2) of material fact (3) made with scienter (4) on which plaintiff relied (5) that proximately [injured him]." *Blackwell*, 440 F.3d at 286 (quoting *ABC Arbitrage v. Tchuruk*, 291 F.3d 336, 348 (5th Cir. 2002)).

1. Material Misstatements and/or Omissions

According to Plaintiffs, they have alleged misstatements and/or omissions by Defendants with the requisite particularity involving the following: (1) the facts surrounding the FDA's inspection of the Cyberonics facility; (2) the nature of the relationship between Cyberonics and the FDA, including the chances and timing of FDA approval for VNS Device use to treat TRD; (3) the facts surrounding, as well as the nature and import of the FDA's non-approvable letter; (4) the efficacy and safety of the VNS System; and (5) the size of the market and the economic need for the device. The Court will address each below.

a. FDA Inspection

Plaintiffs allege that Defendants knew and concealed that, on July 12, 2004, FDA inspectors arrived at Cyberonics to begin an inspection of the facilities. According to Plaintiffs, this is significant because Defendants had previously represented to the investment community that such an inspection would not occur. Indeed, the complaint alleges that during a conference call on January 7, 2004, Defendant Totah stated in relevant part:

> Finally, after the meeting we were advised by the FDA that although normally a manufacturing facility inspection is required for panel track application, such as the one we submitted, based upon our current quality compliance record and the fact that our VNS device platform has not changed, no inspection of Cyberonics manufacturing facility will be required by the FDA. This is a real plus to Cyberonics, as this removes another administrative regulatory step from the submission review and approval process.

Plaintiffs contend that even though this statement might have been accurate when made, Totah had a duty under federal securities law to correct this prior statement when later events rendered the statement misleading to the investing public.

In response, Defendants first argue that Totah's statement of January 7, 2004 made no assessment on the part of Cyberonics about whether an inspection was required; rather, Totah merely relayed to shareholders what Cyberonics had been told by the FDA. Therefore, Defendants contend that there was no duty to disclose the July inspection. Defendants also suggest that the inspection of Cyberonics' facilities starting in July 2004 was not related to the PMA-S and that Plaintiffs have failed to point to any facts indicting that the inspection resulted from anything other than a routine inspection arising out of the long-approved use of the VNS Device to treat epilepsy. In support of their position, Defendants point to the inspection report, which makes no mentioned of the PMA-S.

Contrary to Defendants' position, the Court finds that Plaintiffs adequately alleged that the July 2004 FDA inspection was related to the PMA-S. In paragraph 94 of the complaint, Plaintiffs specifically allege that Defendants concealed that FDA inspectors "had descended on Cyberonics to begin an inspection of the Company's facilities, systems and records *in connection with its PMA-S*."[5] Although Defendants contend that the inspection was not related to the PMA-S, the Court must consider the factual allegations in the complaint as true and must not endeavor to resolve these types of factual disputes during this stage of the litigation. *See Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982).

As for Defendants' position that they had no duty to correct the January 7, 2004 statement as a result of the inspection in July, the Court agrees. Most significantly, the statement in January 2004 did not constitute an affirmative misrepresentation on the part of Cyberonics. Instead, as Defendants note and as the language expressly indicates, Totah merely relayed information that was conveyed to Cyberonics by the FDA. Plaintiffs do not challenge Totah's January 7, 2004

[5]Dkt. #27, ¶ 94 (emphasis added).

characterization of the FDA's communication as untrue, and thus, cannot argue that affirmative misrepresentations were made by Cyberonics, which the company had a duty to correct. Rather, Plaintiffs' position leads to the following inquiry: After relaying accurate information in January 2004 conveyed by the FDA to Cyberonics, did Cyberonics omit material information by not informing the investment community that a facility inspection began in July 2004? Given that Plaintiffs do not contest the accuracy of the statement when made, the fact that the January 2004 statement merely relays information conveyed to Cyberonics regarding the FDA's intentions, and, finally, the time span of several months separating the events, the Court concludes that the allegation does not amount to an omission of a material fact necessary to make a statement by Cyberonics not misleading.[6] *See* 17 C.F.R. § 240.10b-5.

b. FDA and Cyberonics Relationship

Plaintiffs accuse Defendants of falsely representing the nature of their relationship with the FDA in terms of the approval process for the PMA-S. Specifically, Plaintiffs point to Defendants' June 15, 2004 press release in which Defendants stated, "Cyberonics is looking forward to working with the FDA to finalize labeling that will ensure informed use of VNS Therapy, implement the Panel's recommendations, and obtain a timely approvability decision." According to Plaintiffs, this statement "implied that approvability hinged on a successful panel review that, once achieved, would

[6]The Court does not suggest that SEC Rule 10b-5 imposes a requirement of contemporaneity regarding a defendant's duty not to omit material facts necessary to make a statement not misleading. Indeed, as the Fifth Circuit has noted, "at least facially, it appears that defendants have a duty under Rule 10b-5 to correct statements if those statements have become materially misleading in light of subsequent events." *Rubinstein v. Collins*, 20 F.3d 160, 170 n.41 (5th Cir. 1994). In this Court's view, however, imposing this duty on a defendant based on the facts alleged in this complaint would judicially impose a requirement not contemplated by Rule 10b-5.

propel the application to the end of the process, product labeling, and the approvability decision." Plaintiffs also cite the following language in the June 15, 2004 press release:

> Today's Panel vote suggests that not only was there agreement on the significant unmet need, but also that the comprehensive one-year data and analyses on 460 patients included in Cyberonics' PMA-Supplement demonstrated the safety and effectiveness of VNS Therapy as an adjunctive long-term treatment for chronic or recurrent treatment-resistant depression.

Such language, Plaintiffs insist, misled the investment community because Defendants knew from ongoing communications with the FDA that certain deficiencies existed within its PMA-S.

In response, Defendants urge that these alleged misrepresentations were simply optimistic statements regarding the status of the approval process—a process that ultimately proved successful in February 2005 when the device was deemed approvable. As Defendants note, it is well established that generalized positive statements about a company's progress are not a basis for liability. *See Nathenson v. Zonagen Inc.*, 267 F.3d 400, 419 (5th Cir. 2001). In this case, Plaintiffs' allegations are insufficient because they fail to identify with particularity any reason why these statements are either not true or why they should not be considered mere "puffing." *See id.* In the first instance, Defendants' statement regarding "looking forward to working with the FDA" largely resembles the nature of the process that apparently occurred according to the complaint. That is, Defendants engaged in a process of communication with the FDA to remedy deficiencies in their PMA-S, which Plaintiffs cannot dispute was approved only months later.

Nor does Defendants' second statement in the press release regarding the panel's vote to recommend approval constitute a material misrepresentation under the facts alleged in the complaint. Quite simply, characterizing the vote as a *suggestion* that the panel agreed upon a need for TRD treatment and that the VNS Device was safe and effective does not implicate section 10(b) and Rule

10b-5. That some members of the panel had concerns about the PMA-S and actually voted not to recommend approval does not alter the fact that the vote resulted in a favorable decision for Defendants.

c. The Non-Approvable Letter

Next, Plaintiffs assert that Defendants misrepresented the facts surrounding, as well as the nature and import of the FDA's August 12, 2004 non-approvable letter. The thrust of Plaintiffs' allegations focuses on Cyberonics' press release and Defendant Cummins' statements in response to the FDA's August 12 letter. In sum, Plaintiffs contend that Defendants' expression of shock and disappointment at the non-approvable letter was misleading because Defendants should have expected the result from its communications with the FDA. Under the facts alleged in this case, the statements cited by Plaintiffs do not amount to actionable statements under section 10(b) and Rule 10b-5.

d. The VNS System

Plaintiffs' complaint also alleges that Defendants misrepresented the safety and efficacy of the VNS Device. Once again, Plaintiffs point to numerous statements made by Defendants outside of the class period—some more than two years prior to the beginning of the class period—that are simply not relevant in assessing the sufficiency of the complaint for the period at issue. Of the comments made during the class period regarding the safety and efficacy of the product, the Court first considers the language in the June 15, 2004 press release. As the Court has already noted, the Defendants' statements characterizing the panel's vote to recommend approval as a *suggestion* that the panel agreed that the VNS Device was safe and effective does not implicate section 10(b) and Rule 10b-5.

As for other class period comments and statements, Plaintiffs do not allege that Defendants failed to disclose specific data or information regarding its clinical trials. Nor do Plaintiffs specifically allege that Defendants concealed data to render the results misleading. Rather, Plaintiffs complain about the interpretation of certain data, as well as Defendants' alleged failure to disclose FDA concerns about the safety and effectiveness of the VNS Device. In light of the panel's vote to recommend approval in June 2004 and the eventual issuance in February 2005 of the approvable letter, Plaintiffs' position regarding Defendants' misrepresentations is greatly undermined. Accordingly, the Court cannot conclude under the facts alleged that Plaintiffs have identified misstatements and/or omissions by Defendants involving the safety and effectiveness of the VNS Device.

e. Market Size and Economic Need

Plaintiffs also contend that Defendants misrepresented the potential market size and economic need for the VNS Device use in treatment of TRD. In particular, Plaintiffs point to two statements by Defendants: (1) that there was a huge patent-protected U.S. market opportunity based on a potential of over 4.4 million patients in need, and "4.4 million patients per Datamonitor x $15,000 ASP = $66 billion;" and (2) that the product had received widespread support by psychiatric thought leaders, patients and *payers*. In response, Defendants contend that Plaintiffs do not actually assert that these alleged misrepresentations are false because the market potential estimates are inaccurate or that some payers did not support approval. Rather, Defendants accuse Plaintiffs of using this argument to mask Plaintiffs' position that the VNS Device had no market at all, which Defendants knew because Defendants were aware that it was not safe and effective. The Court agrees.

Notwithstanding that Plaintiffs largely point to statements and representations made outside the proposed class period, the statements regarding market size and economic need standing alone cannot be called material misrepresentations or omissions under the facts alleged. Specifically, Plaintiffs do not challenge Defendants' estimates that there are 4.4 million individuals suffering from TRD or that such a number represents approximately a $66 billion market for their device. The Court has not located any allegation in the complaint suggesting Cyberonics represented to the investment community that it expected to or guaranteed to sell its VNS Device to each of those 4.4 million individuals. Instead, the figures appear to be no more than estimates of potential market size, which Plaintiffs have not challenged except to assert that Defendants should have known the product's ineffectiveness would result in the estimated market not materializing.

As for alleged misrepresentation regarding "payer" support for the device, the Court finds no basis in the complaint for finding the use of this word a misrepresentation. Indeed, in their response to Defendants' Motion, Plaintiffs point only to a single negative payer evaluation in August 2005. Yet the fact that a payer ultimately found the product ineffective does not make the disputed statement false or misleading. Rather, like the allegations regarding the market estimates, Plaintiffs' position regarding this statement seems to be another attack on the overall effectiveness of the product–an attack which this Court has deemed insufficient under the facts alleged.

2. Scienter

The Fifth Circuit has defined scienter as an "intent to deceive, manipulate, or defraud or that severe recklessness in which the danger of misleading buyers or sellers is either known to the defendant or is so obvious that the defendant must have been aware of it." *Southland*, 365 F.3d at 366 (internal citations, quotations and ellipsis omitted). Severe recklessness is "limited to those

highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence, but an extreme departure from the standards of ordinary care." *Broad v. Rockwell Int'l Corp.*, 642 F.2d 929, 961-62 (5th Cir. 1981). Plaintiff must allege facts sufficient to raise a strong inference of scienter with respect to each individual defendant. *See Southland*, 365 F.3d at 365 (holding that plaintiffs claiming securities fraud against multiple defendants must "distinguish among those they sue and enlighten *each defendant* as to his or her particular part in the alleged fraud") (emphasis in the original). In determining whether Plaintiffs have alleged facts sufficient to give rise to a strong inference of scienter, the Court should consider the factual allegations contained in the complaint in their entirety. *See Barrie v. Intervoice-Brite, Inc.*, 397 F.3d 249, 250-60 (5th Cir. 2005).

The Court notes that the absence of material misrepresentations in the complaint effectively negates any possibly that Plaintiffs have raised a strong inference of scienter. Plaintiffs essentially rely on the stock transactions of the individual defendants as their only circumstantial evidence that is remotely probative.[7] As the Fifth Circuit has made clear, however, evidence of this nature indicating motive and opportunity, without more, is usually insufficient to establish the necessary showing of scienter. *See Goldstein v. MCI WorldCom*, 340 F.3d 238, 246 (5th Cir. 2003) (citing *Nathenson* 267 F.3d at 412). There, the court explained,

> Appropriate allegations of motive and opportunity may meaningfully enhance the strength of the inference of scienter, but it would seem to be a rare set of circumstances indeed where those allegations alone are both sufficiently persuasive to give rise to a scienter inference of the necessary strength and yet at the same time there is no basis for further allegations also supportive of that inference.

---

[7]In their opposition to Defendants' motion, Plaintiffs also point to alleged internal documents that are referenced in the Senate Report. These documents and some of the related allegations are not contained in Plaintiffs' complaint. Therefore, the Court will not consider the information in assessing the sufficiency of the complaint at issue.

Id. Considering the factual allegations contained in this complaint, the Court concludes that this case does not represent that rare set of circumstances where this type of evidence alone will give rise to a scienter inference of the necessary strength.[8]

3. Loss Causation

Perhaps the issue most fiercely contested by Defendants is Plaintiffs' obligation to properly allege "loss causation" in their complaint. As the Supreme Court has recently explained, alleging "loss causation" sufficiently entails providing "defendants with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the alleged misrepresentation." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347 (2005). In *Dura*, the plaintiffs filed a securities fraud class action, alleging that the defendants made misrepresentations about future FDA approval of a new device, leading respondents to purchase Dura securities at an artificially inflated price. *Id*. at 339-40. The district court dismissed the case, finding that the complaint failed to adequately allege loss causation. *Id*. at 340. The Ninth Circuit reversed, finding that a plaintiff can satisfy the loss causation requirement simply by alleging that a security's price at the time of purchase was inflated because of the misrepresentation. *Id.*

The Supreme Court reversed the Ninth Circuit's holding, finding that plaintiffs failed to adequately allege proximate causation. *Id*. at 345-46. Specifically, the Supreme Court held that a plaintiff cannot satisfy the loss causation requirement of Section 10b-5 by simply alleging in the

---

[8]The class period transactions cited by Plaintiffs involve stock sales by Defendants Rudolph, Jennings, Cheney, and Totah during the period of June 18-28, 2004. Plaintiffs point out that Defendant Rudolph sold approximately 90% of his stock during this time, and Defendant Jennings sold approximately 17% of his stock. There is no indication of stock transactions by Defendant Cummins.

complaint and later establishing that the purchase price of the security on the date of purchase was inflated because of the misrepresentation. *Id*. As to the inflated price, the Court explained,

> Given the tangle of factors affecting price, the most logic alone permits us to say is that the higher purchase price will *sometimes* play a role in bringing about a future loss. It may prove to be a necessary condition of any such loss, and in that sense one might say that the inflated purchase price suggests that the misrepresentation (using language the Ninth Circuit used) "touches upon" a later economic loss. But, even if that is so, it is insufficient. To "touch upon" a loss is not to cause a loss, and it is the latter that the law requires. 15 U.S.C. § 78u-4(b)(4).

Id. at 343 (emphasis in original). To allege a sufficient cause of action, a plaintiff must allege that the share price fell significantly after the truth about the misstatement or omission became known. *Id*. at 346-47. Because the plaintiffs' complaint in *Dura* did not contain any reference to falling share prices, the Court ultimately found the district court's dismissal appropriate. *Id*. at 347.

Although the defect in *Dura* was the failure to allege a drop in share prices or loss, it is clear that the law also requires an explanation of the causal connection between the loss and the misrepresentation. The causation requirement "derives its function from the standard rule of tort law that the plaintiff must allege and prove that but for the defendant's wrongdoing, the plaintiff would not have incurred the harm of which he complains." *Newton v. Merrill Lynch, Pierce, Fenner & Smith*, 259 F.3d 154, 177 (3d Cir. 2001) (citing *Bastian v. Petren Res. Corp.*, 892 F.2d 680, 685 (7th Cir.1990) (internal quotations omitted)). This rule is otherwise referred to as "proximate cause." As to this point, the Fifth Circuit Court of Appeals has explained:

> The plaintiff must prove not only that, had he known the truth, he would not have acted, but in addition that the untruth was in some reasonably direct, or proximate, way responsible for his loss. . . . If the investment decision is induced by misstatements or omissions that are material and that were relied on by the claimant, but are not the proximate reason for his pecuniary loss, recovery under the Rule is not permitted.

Huddleston v. Herman & MacLean, 640 F.2d 534, 549 (5th Cir. 1981). The proximate cause requirement "prevents section 10(b) and Rule 10b-5 from becoming a system of investor insurance." *Rousseff v. E.F. Hutton Co.*, 843 F.2d 1326, 1329 (11th Cir.1988).

In this case, Plaintiffs' complaint does not suffer from the same defect that existed in *Dura*—a failure to allege a drop in share price. In fact, Plaintiffs assert that Defendants' "false and misleading statements, representations and concealment of material information in connection with its PMA-S application caused the price of Cyberonics shares to decline over 50% from its peak of $38.40 on June 16, 2004, resulting in millions of dollars of damages to investors."[9] Additionally, Plaintiffs' complaint alleges the following:

> 120. The almost 40% decline in Cyberonics stock on August 12, 2004, and the 7.9% decline in Cyberonics' stock price on October 1, 2004, at the end of the class period were the direct result of the unraveling of the nature and extent of defendants' fraud finally being revealed to investors and the market. The timing and magnitude of Cyberonics stock price decline negate any inference that the loss suffered by plaintiff and other Class members were caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants' fraudulent conduct.
>
> 121. On the days in which Cyberonics stock price fell almost 40% and 7.9% as a result of defendants' fraud being revealed, the Standard and Poor's 500 securities index was flat. The economic loss, i.e. damages, suffered by plaintiff and other members of the Class was a direct result of defendants' fraudulent scheme to artificially inflate Cyberonics stock price and the subsequent significant decline in the value of Cyberonics stock when defendants' prior misrepresentations and other fraudulent conduct was revealed.

Although the allegations cited above adequately address the loss aspect of the loss causation requirement, the complaint fails to sufficiently explain the causal connection between the loss and Defendants' actions.

---

[9]Dkt. #27, ¶ 14.

In the Court's view, the deficiency as to the loss causation element is borne largely out of Plaintiffs' failure to point to actionable conduct on the part of Defendants. According to factual allegations in the complaint, the losses that occurred on August 12, 2004 and October 1, 2004 followed events and statements by entities other than Defendants. Specifically, the decline on August 12, 2004 followed the announcement regarding the FDA non-approvable letter. Moreover, the October 1, 2004 decline followed an announcement by ANSI that it was dropping its merger bid. Although Plaintiffs allege that these events exposed Defendants' fraudulent conduct and pattern of misrepresentation, the Court has already found that Plaintiffs have failed to actually identify conduct of that nature on the part of Defendants. Absent some actionable conduct by Defendants, the Court cannot find that Plaintiffs have alleged proximate causation and is left only with the inference that the losses were caused by other factors, i.e., the FDA's non-approvable letter and ANSI's decision to drop its merger bid after Cyberonics expressed its disinterest.[10]

4. Section 20(a) Claim

Along with the Rule 10b-5 claim, Plaintiffs allege that the individual Defendants violated section 20(a) of the Exchange Act. 15 U.S.C. § 78t(a) (2002). Section 20(a) imposes control person liability on "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter." *Id.* However, section 20(a) liability may not be imposed unless there is an underlying violation of the Securities Exchange Act. *See* 15 U.S.C. § 78t(a); *Dennis v. General Imaging, Inc.*, 918 F.2d 496, 509 (5th Cir. 1990). Because there is no viable underlying violation alleged against

[10]The Court's decision should not be taken as an indication that it has imposed the heightened pleading requirement of Rule 9(b) to the loss causation element. *See Dura*, 544 U.S. at 346-47. Instead, the Court concludes only that proximate causation in this case has not been adequately alleged when the complaint does not point to any actionable conduct by Defendants that could have caused the losses.

the individual Defendants, the derivative section 20(a) claim for controlling person liability also must fail. The section 20(a) cause of action will therefore be dismissed also.

C. Leave to Amend

In their opposition to Defendants' motion, Plaintiffs alternatively seek leave to amend their complaint to remedy any deficiencies and to incorporate subsequently uncovered facts. Leave to amend should be freely granted when justice requires. FED. R. CIV. P. 15(a). Although some of the deficiencies in Plaintiffs' complaint might well extend beyond the point of cure, there is a strong presumption in favor of granting leave to amend in cases of this nature. *See Financial Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 291 (5th Cir. 2006). As Plaintiffs have not previously sought leave to amend, the Court finds that allowing Plaintiffs leave to amend in this instance is appropriate.

Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss Plaintiffs' Consolidated Complaint is GRANTED and Plaintiffs' Motion to Take Judicial Notice of Certain Facts is GRANTED in part and DENIED in part. Accordingly, Plaintiffs' claims are hereby DISMISSED. Plaintiffs shall have thirty (30) days leave within which to file an amended complaint.

Signed at Houston, Texas on July 18, 2006.

Gray H. Miller
United States District Judge